IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(s):	Hans-Werner Heinrich	CONF. NO.	4120
SERIAL NO.:	09/786,725	ART UNIT:	PCT
FILING DATE:	04/23/2001	EXAMINER:	Williams, Karen M
TITLE:	DIAGNOSTIC METHOD FOR DETECTING DISTURBANCES IN THE PANCREAS		
ATTORNEY DOCKET NO.:	101195-44		

Commissioner for Patents
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DECLARATION OF ---------

1. My name is Ph.Dr. Hans Werner Heinrich. I am a citizen of GERMANY I reside at D-17489 GREIFSWALD

2. My educational background is in the field of VET. MED. I obtained the degree(s) of DRS. from ACADEMY OF SCIENCES

3. I am DIRECTOR (present position) My vitae is shown in Exhibit I.

4. I am the author of ----------in this field summarized in Exhibit II.

5. I have carefully studied the specification and was involved in the preparation of US patent application US 09/786,725.

6. I am familiar with the references cited by the examiner in this application.

7. The Szigoleit et al. reference discloses a method for the detection of elevated elastase 1 levels in the serum of patients.

7. The Scheefers et al. reference discloses a method for obtaining highly specific elastase 1 antibodies for diagnosis and monitoring pancreatitis.

8. Both documents describe only the detection of elastase 1.

9. The present invention describes a method for detecting elastase 1, 2 and 3 isoenzymes.

10. Elastase enzymes are digested when they reach the intestinal tract. The antibodies described in Scheefers et al. are not able in many cases to bind to the snatches of the digested enzyme, because they are only specific for one amino acid sequence.

11. Antibodies of present invention are specific for several and different parts of amino acid sequences of those isoenzymes. It was an unexpected effect that antibodies of present invention are able to detect even those portions of digested elastase isoforms.

12. Szigoleit et al. is useable only in serum, Scheefers et al. is not as effective as present invention in detecting elastase in stool. The advantage of the present invention over the prior art is that it is useable in serum, stool and other secretions and excretions.

13. Both Szigoleit et al. and Scheefers et al describe only

detection of elastase 1 and not detection of further isoenzymes as is possible by using the presently claimed procedure.

14. A diagnostic test using the polyclonal antibodies from Szigoleit et al. and Scheefers et al. would give false results because the polyclonal antibodies are derived from enzyme preparations of Szigoleit et al. and of Scheefers et al. are a large mixture of antibodies which also bind amylases, lipases, chymotrypsin and elastases from pork or other animals.

15. Therefore, the polyclonal antibodies from Szigoleit and Scheefers are not appropriate for the diagnostic of chronic pancreatitis.

16. Unlike the cited references, the polyclonal antibodies of present invention are highly specific for epitopes of elastases III A/III B and elastases II A/II B, which surprisingly only exist in these proteins.

17. Cross reactions with other human pancreatic enzymes are demonstrably excluded by the claimed procedure as well as cross reactions with animal elastases, i.e. pork elastases. This is very important, because preparations of pork elastases are used for substitution in the treatment of patients with chronic pancreatitis.

18. The differences between the presently claimed procedure and the prior art leads to a large advantages in diagnoses over the state of the art.

19. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these

statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Declarant

09/02/2010
Date

Respectfully submitted,

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